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Page 1 of 1

Application Number	10/022,138
Filing Date	December 13, 2001
First Named Inventor	SCHULTZ et al.
Group Art Unit	1616
Examiner Name	Not yet assigned
Attorney Docket Number	ORT-1548

**U.S. PATENT DOCUMENTS** U.S. Patent Document Pages, Columns, Lines, Name of Patentee or Applicant Examiner Cite Kind Code<sup>2</sup> where relevant passages or of Cited Document Number (if known) relevant figures appear No.1

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#### **FOREIGN PATENT DOCUMENTS** Foreign Patent Document Date of Publication Pages, Columns, Lines, of Cited Document where relevant Name of Patentee or Examiner Cite passages or relevant mm-dd-yyyy T٩ Applicant of Cited Document figures appear Initials Office<sup>3</sup> Number<sup>4</sup> KindCode5 No.1 EP 0657161 06-14-1995 Α Akzo Nobel NV EΡ 0587047 Α Jenapharm GMBH 03-16-1994

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		JAIN, et al.: "Stability of a hydrophobic drug in presence of hydrous and anhydrous lactose". European Journal of Pharmaceutics and Biopharmaceutics, Elsevier Science Publishers B.V., Amsterdam, NL., vol 46, no. 2, Sept. 1998, pgs. 177-182, XP004257039, ISSN: 0939-6411.				

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	5,382,434	А	de Haan et al.	01/17/1995	
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Initials*	No. <sup>1</sup>	publisher, city and/or country where published	
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	1	BUCKTON et al.; "The influence of additives on the recrystallisation of amorphous spray dried	
	-+	lactose"; International Journal of Pharmaceutics, 121 (1995), pp 81-87.	
		HUTTENRAUCH et al.; "Mechanical Activation of Pharmaceutical Systems", Pharmaceutical Research 1985, pp 302-306.	
0103			
5	7	LIEBERMAN et al.; "Pharmaceutical Dosage Forms", Marcel Dekker, Inc., Vol. 2 (1990), pp 213-217 and 327-329.	
•		MORITA et al.; "Physicochemical Properties of Crystalline Lactose. II <sup>1</sup> . Effect of crystallinity on Mechanical and Structural Properties.", Chem. Pharm. Bull., 32(10) 1984, pp 4076-4083.	
		SEBHATU et al.; "Assessment of the degree of disorder in crystaline solids by isothermal microcalorimetry", International Journal of Pharmaceutics 104 (1994), pp 135-144.	
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